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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MORRISON & FOERSTER LLP
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,952	Applicant(s) MCCABE ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>072806</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 5-27 in the reply filed on 14 August 2008 is acknowledged.

Claims 1-4 and 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 August 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 5-9, 12-16, 18, 20, 22, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Livesey (US 4865871).

With respect to claim 5, Livesey discloses a kit comprising a self-contained cell culture vessel that includes a sample holder (Figure 4:100) for accommodating cell reservoirs (Figure 4:111) and media reservoirs (Figure 4:111). This is disclosed in column 17, lines 6-17. Column 15, lines 3-21 state that the sample holder is positioned within a gas reservoir (Figure 4:90) capable of being used to hold a dry nitrogen gas.

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Column 8, lines 14-45 indicate that cells and a cryoprotectant are disposed in the cell reservoir, and column 8, lines 39-45 specifically indicate that the cyroprotectants are added to a cell culture.

With respect to claim 6, Livesey discloses the kit set forth in claim 5 wherein the kit is maintained at subzero temperatures. Livesey indicates in column 15, lines 33-39 that the kit includes a container (Figure 4:99) for holding cryogenic cooling means.

With respect to claim 7, Livesey discloses the kit set forth in claim 5 wherein a plurality of internal chambers are provided. The cryogenic dewar (99), the gas chamber (90), and each of the individual tissue wells (111) constitute internal chambers.

With respect to claim 8, Livesey discloses the kit set forth in claim 7 wherein the cryogenic dewar (99) includes a sealable top opening through which the gas reservoir is introduced. The gas reservoir further includes a plurality of seals (Figure 4:97) that regulate the introduction of various gases for drying, treatment and flushing. This is disclosed in 15, lines 8-21. Furthermore, the cell reservoirs and media reservoirs (111) are capable of fluid communication with the internal chamber of the gas reservoir. As previously noted, the vessel as a whole is capable of being sealed (see Figure 2), and is made of a material capable of withstanding subzero temperatures.

With respect to claims 8 and 25, Livesey discloses the kit set forth in claim 8 wherein a liquid impermeable flexible partition (Figure 6:114) is disposed within the internal chamber of the gas reservoir (90). Column 17, lines 6-29 state that the membranes are positioned over the cell and media reservoirs (111) and permit gas transfer to the cell and media reservoirs. Accordingly, a first space is formed within the

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cell and media reservoirs that are capable of containing a liquid, and a second space is formed within the gas reservoir capable of maintaining dry nitrogen gases used in dehydration processes. Livesey teaches that the edges of the membrane are sealed to each reservoir side wall (Figure 6:115) using special vacuum adhesives.

With respect to claim 12, Livesey discloses the kit set forth in claim 7 wherein the gas reservoir (90) is a self-contained capsule disposed within the internal chamber of the cryogenic dewar (90).

With respect to claims 13-15 and 14, Livesey discloses the kit set forth in claim 7 wherein the gas reservoir (90) is disposed outside of and surrounds the internal chambers established by the cell and media reservoirs (111).

With respect to claim 16, Livesey discloses the kit set forth in claim 8 wherein the sealable top opening of the cryogenic dewar is a mechanically operated valve.

Mechanically operated valves (97) are additionally used to introduce fluids to the gas reservoir.

With respect to claims 18, 20, 22 and 26, Livesey discloses the kit set forth in claim 8 wherein a temperature measuring device is used to monitor and control the temperature within the system. The kit includes a plurality of chambers and channels that serve to connect the measuring device to each of the multiple components of the system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 2) Claims 5-10, 13, 15-18, 20, 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537).

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With respect to claims 5 and 7, Rajotte discloses a kit comprising a self-contained cell culture vessel comprising a cell reservoir and a media reservoir in the form of detachable pouches (Figure 6:3a) located above an internal chamber (Figure 6:4). Rajotte teaches in column 4, lines 20-60 that cells, DMSO cryoprotectant, and cell culture media are retained within the upper portions. Rajotte, however, does not indicate that a gas reservoir is provided.

Wilson discloses a tissue flask for cell culture that comprises a culture chamber (Figure 5:40) bounded on one side by a gas permeable membrane (Figure 5:120) in communication with a gas reservoir (Figure 5:190). Column 7, lines 47-67 indicate that critical gases are moved to and from the culture chamber through the gas permeable membrane.

Rajotte and Wilson are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to provide the Rajotte kit with an additional storage unit at the upper portion capable of serving as a gas reservoir. Prior to and following freezing, this additional reservoir would provide the cell culture with necessary critical gases required for growth and maintenance. Wilson teaches that the coupling of a gas reservoir to a cell culture compartment using a gas permeable membrane is well known in the art. Gas permeable membranes such as the one described in Wilson are formed from materials well known in the art, and could be incorporated into the Rajotte kit with only minor structural alteration.

With respect to claim 6, Rajotte and Wilson disclose the apparatus set forth in claim 5. In addition, Rajotte indicates that the kit is intended for use at subzero temperatures as a cryopreservation bag.

With respect to claim 8, Rajotte and Wilson disclose the apparatus set forth in claim 7. Rajotte additionally states that the reservoirs (3a) are in communication with an internal chamber (4), and that this communication is achieved through an opening that can be heat sealed upon removal of a reservoir. As previously noted, Wilson discloses the use of a gas reservoir sealed using a gas permeable membrane. Wilson further states that the gas reservoir is sealed at a gas access opening (Figure 3:140).

With respect to claims 9 and 10, Rajotte and Wilson disclose the apparatus set forth in claim 7. As previously described, Wilson describes the use of a flexible partition for separating a first liquid space from a second space capable of containing a gas. Wilson teaches that the edges of the partition are sealed to prevent liquid communication between each side of the partition. Wilson further teaches that the membrane is a polymeric material naturally expandable in character, and that the other surrounding portions of the gas reservoir are formed from a rigid material.

With respect to claims 13 and 15, Rajotte and Wilson disclose the apparatus set forth in claim 7. Rajotte describes the use of self-contained capsules sealably connected to an internal chamber.

With respect to claims 16, 17 and 25, Rajotte and Wilson disclose the apparatus set forth in claim 8. Rajotte teaches that the cell and media portions (3a) are sealed to the internal chamber (4) using heat seals that are temperature sensitive and work to restrict access upon the application of heat. Additionally, safety seals are considered to be well known in the art.

With respect to claims 18, 20, 22, 26 and 27, Rajotte and Wilson disclose the apparatus set forth in claim 8. Rajotte additionally teaches that thermocouples are distributed within the kit in order to detect temperature throughout each reservoir. The reservoir is in turn connected to inlet and outlet ports and channels. This is described in column 3, lines 3-15. Likewise, Wilson teaches that it is critical in cell culture systems to regulate pH and critical gas levels in order to optimize growth. The use of sensors is required to effectively monitor pH, oxygen and carbon dioxide.

3) Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537) as applied to claims 8 and 18, and further in view of Mullen (US 5679565).

Rajotte and Wilson disclose the apparatus set forth in claims 8 and 18 as set forth in the 35 U.S.C. 103 rejections above. As previously noted, inlet and outlet ports are provided for adding and removing additional material through a fluid channel to the cell and/or media reservoirs. This is disclosed by Rajotte in column 4, lines 20-60. Figure 6 indicates that the fluid channels comprise septa that serve as valves to

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regulate flow. Furthermore, essentially any number of additional detachable pouches in the form of absorbent chambers could be added to the top portion of the Rajotte device. Rajotte, however, does not expressly indicate that a cell filter is provided.

Mullen discloses a means for storing and preserving tissues that includes an internal compartment (Figure 1:12) serviced by a channel (Figure 1:28) for conveying fluids. Mullen teaches in column 5, lines 7-22 that a cell filter (Figure 1:22) is attached to the channel.

Rajotte and Mullen are analogous art because they are from the same field of endeavor regarding tissue preservation means.

At the time of the invention, it would have been obvious to provide the kit of Rajotte with a filter means at the inlet/outlet channel capable of retaining tissue cells within the kit while preventing the passage of contaminants. Filter means, as evidenced by Mullen, are considered to be well known in the cell culture art, and are beneficial because they serve to prevent contamination. The cell filter of Mullen would serve the additional advantage if incorporated into the Rajotte kit of maintaining stored tissue inside the reservoir, thereby preventing undesirable tissue loss during the removal of fluids.

4) Claims 19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajotte (US 5863715) in view of Wilson (US 5693537) as applied to claims 18 and 20, and further in view of Anderson (US 20060246490).

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Rajotte and Wilson disclose the kit set forth in claims 18 and 20 as set forth in the 35 U.S.C. 103 rejections above, however do not expressly state that the measuring device includes a MEMS. Furthermore, Rajotte and Wilson do not teach the use of ball valves for regulating fluid movement.

Anderson discloses a substrate for measuring the presence of biochemical analytes in a sample solution. Anderson teaches in paragraph [0183] that ball valves are common means for controlling fluid motion in a channel. Anderson additionally teaches in paragraphs [0338] and [0339] that micro electro mechanical systems are likewise commonly used as valve means.

Rajotte and Anderson are analogous art because they are from the same field of endeavor regarding biochemical analysis devices.

At the time of the invention, it would have been obvious to provide any known means for regulating fluid flow in the Rajotte device as a substitute for the mechanisms already disclosed by Rajotte. Anderson teaches that MEMS and ball valve structures are commonly implemented in microfluidic systems, and that each represents a functionally equivalent way to restrict fluid flow. Accordingly, it would have been obvious to implement these well known features in the Rajotte kit in order to predictably and effectively control the movement of fluid to and from the various reservoirs.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Wang (US 20020168759) and Irr (US 5209745) references disclose the state of the art regarding cryopreservation systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797